

REMARKSA. The rejection under 35 U.S.C. 112, first paragraph, for lack of enablement

In the Final Office Action of November 18, 2003, claims 8-22 were rejected under 35 U.S.C. 112, first paragraph, because the specification is allegedly not enabling for combining reference pressure data with absolute pressure data to produce corrected cardiac pressure data and transferring the corrected pressure data to a remote center. Applicants traversed and first, with regard to combining reference pressure data with absolute pressure data to produce corrected cardiac pressure data, pointed to disclosure in the application at pages 12-13, where the following description was provided:

Further, IRM 20 and EPR 24 are adapted to transfer time stamped long term barometric pressure data to enable *correction of cardiac pressure readings due to barometric pressure* uplinked from Chronicle[□], (IMD 10) to IRM 20.

EPR 24 is generally carried by patient 12 or a belt implement 32 or is kept in close proximity to patient 12. EPR 24 is used to derive reference pressure data for use in combination with absolute pressure derived from Chronicle[□] (IMD 10). Various embodiments of this device are disclosed in U.S. Patent No. 6,152,885 issued to Taepke, which patent is incorporated herein by reference in its entirety. Similarly, U.S. Patent No. 5,810,735 to Halperin et al, discloses external patient reference sensors of internal sensors.

In the Advisory Action of February 2, 2004, the examiner contends that the disclosure identified fails to overcome the rejection because Halperin is not incorporated by reference and Taepke is not properly incorporated by reference. Whether or not Halperin and/or Taepke are incorporated by reference, the rejection is

without basis. However, applicants submit that Taepke is properly incorporated. The noted provision of MPEP 608.01(p) that "particular attention should be directed to specific portions of the referenced document..." is met. The passage in the application as quoted above states that Taepke is incorporated "in its entirety." Thus, particular attention is directed by the application to *the entire contents* of Taepke, because that is where the subject matter being incorporated by reference can be found.

Enablement is a question of law to be determined as of the date of filing the application. The requirement is only for disclosure of sufficient information to enable one skilled in the art to make and use the claimed invention without undue experimentation. As to enablement for the production of corrected cardiac pressure data, the above quoted passage from the application directs one skilled in the art to combine reference pressure data with absolute pressure data. The Taepke patent discloses combining reference pressure data with absolute pressure data derived by an IMD and producing corrected pressure data. But, even without Taepke, the subject application nevertheless directs one skilled in the art to combine reference pressure data with absolute pressure data. Those skilled in the art as of the filing date of the subject application would have been familiar with both Halperin and Taepke and thus no undue experimentation would be required.

Further, as acknowledged by the examiner, Taepke discloses the use of an external barometric pressure sensor used in combination with an absolute pressure measurement obtained by an implanted cardiac pressure sensor. Taepke is, however, characterized by the examiner as not disclosing the use of a software module on a personal computer. In view of that contention, claim 8 has been amended to delete the

recitation of a software module resident on the information remote monitor.

In regard to enablement as to the transfer of corrected pressure data to a remote center, the examiner acknowledges that the specification does provide enablement for transferring data to a remote center. But, the examiner's contention is that enablement is absent for both "producing corrected data" and "transferring it to a remote center." Applicants respond that, clearly, the data to be transferred to a remote center is corrected pressure data. Corrected pressure data is what is identified as being produced. As set forth as page 8, lines 23-30: "In the preferred embodiment the IRM is adapted to download data from an external pressure reference (EPR) simultaneous with downloading data from the Chronicle[®] using a wireless telemetry data transfer. The IRM is adapted for connection to a PC to use the PC for data transfer." Then, at pages 12-13, as quoted above, "EPR 24 is used to derive reference pressure data for use in combination with absolute pressure derived from Chronicle[®] (IMD 10). Various embodiments of this device are disclosed in U.S. Patent No. 6,152,885 issued to Taepke..." The device uses stored barometric pressure data to correct the absolute blood pressure data obtained from the IMD. Thus, the data for transfer to the remote center is corrected data derived from combining reference pressure data with absolute pressure data.

The enablement rejection of claim 8 under §112, first paragraph, is without basis and should be withdrawn.

B. The rejection under §103 for obviousness

The rejection of the claims as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309) presents the same issues as

were on appeal. The basis for the rejection is that Halperin discloses an external barometric pressure sensor used in combination with an absolute pressure measurement obtained by an implanted cardiac pressure sensor to produce corrected cardiac pressure data that is telemetered to a programmer. Halperin, however, fails to disclose a communication link between the programmer and a remote data center over which corrected cardiac pressure data is transferred. Krichen is relied upon as teaching a system of transferring information from an implanted medical device to a remote center.

Applicants have previously challenged the rejection as being improper for failing to identify any suggestion to combine the references. As Applicant has argued, Krichen only teaches the desire for an information format which can easily be interpreted and manipulated to allow for interpretation of data received as a "data dump" from an implanted medical device. Thus, the desire and any "suggestion" provided by Krichen are expressly restricted to a situation where an implantable medical device "dumps" its information to a programmer (col. 1, lines 46-53). But, the device of Halperin is not compatible with this type of data transfer.

The examiner has contended that Applicants' characterization of Krichen is in error because what Applicants rely upon is actually a description of the deficiency of the prior art. The passage identified by Applicants describes that in the prior art a data dump from an IMD to the programmer is made in a format, which is not easily transferred via the Internet. (Col. 1, lines 46-59). Krichen provides a converter for information received from an IMD in an initial format, "such as a memory dump format." (Col. 2, lines 52-56). Thus, Krichen operates on the basis of a data dump from the IMD

just as programmers previously operated. The data dump aspect of Krichen is therefore a carry-over from what had been done before. But, whereas the data was sent on by the programmer in the same format, Krichen converts the data to an XML format. Krichen further describes its operations on information that is a data dump from an IMD in column 12, line 29 to column 13, line 15. Accordingly, there has been no misunderstanding by Applicant of the teachings of Krichen.

Thus, as discussed previously, the reach of the teachings of Krichen in regard to what has been termed as "a connection which facilitates transfer of info between programmer and computer" does not extend to information resident on a programmer that is not a "data dump" of implantable medical device information. The office action continues to indicate a failure to grasp the limited focus of Krichen and generalizes what Krichen contemplates in terms of communicating data from an implantable medical device to a remote location. The contention has also been made that Krichen's data transfer is compatible with Halperin. But, in view of the clear misunderstanding by the examiner of Krichen, that conclusion is suspect.

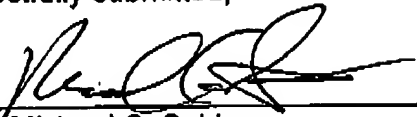
In applying the erroneous and overly broad characterization of the teachings of Krichen, the rejections of the claims, each of which is based on Halperin in combination with Krichen, fail to satisfy the required showing that there be a suggestion or motivation to combine the references. Further, even combining the references fails to result in the claimed subject matter. Thus, as to all claims 8-22, the rejections under §103 are in error, without basis and should be withdrawn.

C. Conclusion

Applicants submit that all pending claims are in condition for allowance and requests that a notice of allowance should be issued in due course.

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Respectfully submitted,

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